

Exhibit D

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., PELVIC) Master File No.
REPAIR SYSTEM PRODUCTS) 2:12-MD-02327
LIABILITY LITIGATION) MDL 2327

5 THIS DOCUMENT RELATES TO
6 PLAINTIFFS:
7 Diane Kropf
Case No. 2:12-cv-01202 JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE
8 Judy Williams
Case No. 2:13-cv-00657
9 Myra Byrd
10 Case No. 2:12-cv-00748
11 Angela Coleman
Case No. 2:12-cv-01267
12 Susan Thamen (Reeves)
13 Case No. 2:12-cv-00279
14 Donna Zoltowski
Case No. 2:12-cv-00811
15
16

17 DEPOSITION OF JOSEPH M. CARBONE, M.D.
18 GENERAL TVT
19 Wednesday, March 16, 2016
20 Danville, Virginia
21 5:18 p.m.
22
23 Reported by: Karen K. Kidwell, RMR, CRR, CLR
24 GOLKOW TECHNOLOGIES, INC.
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1 strike that.

2 It's fair to say, starting in the year
3 2003 through the year 2012, you had a relationship
4 with Ethicon as a consultant physician, correct?

5 A. Yes.

6 Q. And it's fair to say from -- starting in
7 the year 2003 through the year 2012, for each of
8 those years, you received payments from Ethicon for
9 your role as a consultant physician, correct?

10 A. Correct.

11 Q. It's fair to say, between the years 2003
12 to 2012, every single one of those years, you
13 performed work for Ethicon as a consultant physician,
14 correct?

15 A. Correct.

16 Q. It's fair to say before you agreed to be a
17 litigation consultant for Ethicon, you had a ten-year
18 relationship with Ethicon in your role as a
19 consultant physician, correct?

20 A. 2003 till when?

21 Q. To the end of 2012.

22 A. Yes.

23 Q. Do you know how many days -- have you
24 tracked -- strike that.

25 Have you tracked at all how many days out

1 of the year on average you do consultant work for
2 Ethicon?

3 A. No.

4 Q. You don't know one way or the other how
5 many days in the calendar year 2010 you spent
6 consulting with Ethicon?

7 A. No.

8 Q. If someone, perhaps a juror, wanted to
9 know how many calendar days you spent in 2010
10 consulting with Ethicon, would there be a way for
11 them to find that information out?

12 MR. MORIARTY: Objection. Go ahead.

13 THE WITNESS: I wouldn't know.

14 BY MR. JONES:

15 Q. Okay. So that's not information you have
16 at access?

17 A. No.

18 Q. Is it fair to say that, in your consulting
19 work between the years 2003 and 2012 for Ethicon,
20 some of the events you conducted for Ethicon were
21 marketing events?

22 A. Yes.

23 Q. Is it fair to say that, between the years
24 2003 and 2012 in your consulting work for Ethicon,
25 some of your work involved the promotion of Ethicon

1 holding themselves out as an expert in this
2 litigation?

3 A. Well, it means that I don't put as much
4 weight in a Level 4 study, or a low-level study, than
5 I do a high-level study.

6 Q. Is -- are studies that are not, as you
7 call them, Level 1 evidence low-level studies?

8 A. I'm sorry?

9 Q. Are studies that are not Level 1 evidence
10 low-level quality of studies?

11 MR. MORIARTY: Objection.

12 THE WITNESS: Well, it's a spectrum. So I
13 can't -- you know, it's not a dichotomy. So I
14 would say lower.

15 BY MR. JONES:

16 Q. Okay. Are you familiar with the concept
17 of milestone payments?

18 A. I'm sorry?

19 Q. Are you familiar with the concept
20 milestone payments in the context of study -- studies
21 and trials and analyzing data?

22 A. No, I'm not familiar with that.

23 Q. You've never heard the term "milestone
24 payment"?

25 A. I have not.

1 A. That was included in some of the review of
2 case reports.

3 Q. Okay.

4 A. Okay. I'm with you. So 16 is there.

5 Q. All right.

6 A. Keep going.

7 Q. Everything else that Ethicon sent you, how
8 much time did you spend reviewing that?

9 A. Well, it's hard to say because a lot of
10 the articles I had seen before. So not a vast amount
11 of time. I don't know. Those materials back there,
12 I was able to go through relatively quickly. I'd say
13 three or four hours looking through them, with the
14 understanding that a lot of them I had already seen.

15 Q. Okay. And you're talking about medical
16 literature primarily?

17 A. That was all medical literature.

18 Q. All medical literature. Did you review
19 any internal Ethicon documents?

20 A. Some of it is.

21 Q. Some?

22 A. Yeah.

23 Q. Okay. How many?

24 A. Not -- a minority.

25 Q. Very small amount of internal Ethicon

1 articles for you to review?

2 A. A minority. How do you define "very
3 small," right?

4 Q. Did you review more than 100 internal
5 documents?

6 A. No.

7 Q. Did you review more than 50?

8 A. I don't think so.

9 Q. Okay. If you want -- I think I've looked
10 at your reliance list. There's about 10 --

11 A. Yeah.

12 Q. -- 10 --

13 A. Yeah.

14 Q. So 10 or 15 internal documents, okay.

15 A. Yeah. Not many at all.

16 Q. Just so the record -- you reviewed a total
17 of 10 to 15 internal Ethicon documents, correct?

18 A. See the reliance list. Yeah.

19 Q. Fair to say that the bulk of the materials
20 that you're relying on for your opinions in this case
21 come from the medical literature and your clinical
22 experience, correct?

23 A. My knowledge, my training, my experience,
24 the medical literature, my interaction with
25 physicians, the totality of my career.

1 Q. But not the internal Ethicon corporate
2 documents?

3 A. No.

4 Q. Okay. Do you know -- did you review any
5 internal Ethicon design documents?

6 A. I'm sure I may have or may have not. I
7 don't recall specific Ethicon -- what did you say?

8 Q. How about, did you review the design
9 specifications for any of the products that we're
10 discussing here today?

11 A. I don't remember specifically.

12 Q. As you sit here today, you don't have any
13 recollection reviewing the design specifications for
14 the TVT line of products for the Prolift, correct?

15 A. I do not have any specific recollection of
16 those things.

17 Q. Do you know what a -- do you know what --
18 who the company MedScan is?

19 A. MedScan? No.

20 Q. Do you know who Provincia is?

21 A. No.

22 Q. Do you know what an FMEA is?

23 A. FEMA?

24 Q. FMEA.

25 A. Oh, FMEA. No.

1 A. Again, I can't remember specifically. I
2 didn't do that many. When did it come out?

3 Q. Say 2008.

4 A. 2009.

5 Q. Okay. 2008-2009?

6 A. 2008-2009.

7 Q. How come you didn't do very many?

8 A. I -- I like the product. I felt the --
9 there were advantages, disadvantages. I felt one of
10 the advantages was the trocharless insertion; one of
11 the disadvantages was the trocharless insertion. And
12 so I tried it.

13 Q. Sounds like Prosima in theory was a good
14 idea; in practice, maybe not so much?

15 MR. MORIARTY: Objection.

16 Go ahead.

17 THE WITNESS: I can't say I didn't do it
18 because it wasn't a good idea. I just didn't do
19 all that many.

20 BY MR. JONES:

21 Q. Okay. Did you have any failures with
22 Prosimas?

23 A. Yes.

24 Q. Okay. How many?

25 A. I can't remember specifically to the

1 Prosima device. I kind of lumped all -- I can't
2 remember specifically to the Prosima device.

3 Q. What other device?

4 A. What do you mean by that?

5 Q. You're saying -- did you have failures
6 with Prolift as well?

7 A. I did.

8 Q. How many?

9 A. Let's say between Prosima and Prolift, 20,
10 25.

11 Q. Okay. Do you have an exact number?

12 A. No.

13 Q. Have you ever endeavored to do a survey or
14 study of your exact complication rate?

15 MR. MORIARTY: Objection. Go ahead.

16 THE WITNESS: Not my exact complication
17 rate.

18 BY MR. JONES:

19 Q. Okay. How about have you ever done a
20 survey or study to discover your exact failure rate?

21 MR. MORIARTY: Objection. Form.

22 THE WITNESS: Not my exact failure rate.

23

24 BY MR. JONES:

25 Q. So you can't tell us one way or the other

1 your precise success rate with the use of mesh,
2 correct?

3 A. Not --

4 MR. MORIARTY: Objection.

5 THE WITNESS: -- my precise.

6 BY MR. JONES:

7 Q. Have you ever attempted to create a
8 registry with your mesh patients? A registry that
9 tracks your patients, say, five years down the road?

10 A. No.

11 Q. If the TVT-Secur device was still sold by
12 Ethicon today, would you use it?

13 MR. MORIARTY: I'm sorry. Could you just
14 read that back?

15 (Whereupon the Court Reporter read the
16 previous question.)

17 MR. MORIARTY: Thank you.

18 THE WITNESS: Not likely.

19 BY MR. JONES:

20 Q. Why not?

21 A. I like the device fair enough. I think it
22 had a good success and safety profile in my hands. I
23 feel more confident with the Abbrevio that I get the
24 ends of the mesh into the exact position that I want
25 them in in the obturator fascia.

1 sure I get it right.

2 Q. Have you ever been asked by a medical
3 device company other than Ethicon to be an expert in
4 litigation?

5 A. To the best of my recollection, I don't
6 believe any of the medical malpractice cases involved
7 medical devices.

8 Q. Now I've got to ask you again. Yes or no.
9 To the best of your recollection, has a medical
10 device company other than Ethicon ever asked you to
11 act as an expert in litigation?

12 A. Is it the same question?

13 Q. Yes or no?

14 A. Was my answer inadequate?

15 Q. Yes or no?

16 A. Not that I recall.

17 Q. Okay. Perfect.

18 A. Okay.

19 Q. We went back and we did tally up the
20 payments from Exhibit 5.

21 A. Okay.

22 Q. So you have Exhibit 5 in front of you, and
23 we added up those payments from Ethicon to you
24 between the years 2003 to 2012. And the total I'll
25 represent to you is \$452,398.

1 Do you have any reason to disagree with
2 that?

3 A. I have no reason to disagree with that.

4 Q. Okay. And am I correct in saying, between
5 the years 2003 to 2012, Ethicon paid you, according
6 to Exhibit 5, \$452,398?

7 MR. MORIARTY: Objection.

8 Go ahead.

9 THE WITNESS: As a consultant, yes.

10 BY MR. JONES:

11 Q. Did they pay you any other money outside
12 of your role as consultant?

13 A. No.

14 Q. So between the years 2003 to 2012, Ethicon
15 paid you 452,398, correct?

16 A. Correct.

17 Q. Okay. When did Ethicon first contact you
18 to be an expert in this case?

19 A. You know, I don't remember. Obviously
20 sometime before 2003.

21 Q. When did -- I probably did a bad job
22 asking that question.

23 A. I apologize.

24 Q. That's on me. Ethicon -- I assume Ethicon
25 contacted you and said, "Hey, we've got this

1 A. Since 2003, have I experienced, in my use
2 of TVT mesh, roping or curling?

3 Q. (Nodding head up and down.)

4 A. No.

5 Q. Since 2003, in your use of TVT mesh, have
6 you ever seen the mesh deform without
7 supraphysiological tension?

8 A. No.

9 Q. Can TVT mesh cause chronic pain?

10 MR. MORIARTY: Objection. Form.

11 THE WITNESS: I mean, I guess -- I kind of
12 feel like Bill Clinton here. What do you mean
13 by "cause"? Because if you use it in a broad, a
14 very broad sense, anything can cause chronic
15 pain, in a very broad sense.

16 BY MR. JONES:

17 Q. I'm going to ask the question in a
18 yes-or-no form, and then I'm going to ask if you can
19 answer it yes or no.

20 Yes or no: Can TVT mesh cause chronic
21 pain in women?

22 MR. MORIARTY: Objection. Form.

23 THE WITNESS: I cannot answer that
24 specific question.

25 BY MR. JONES:

1 Q. Okay. Yes or no: Can TVT mesh cause
2 chronic dyspareunia?

3 MR. MORIARTY: Objection to form.

4 THE WITNESS: Again, I cannot answer that
5 specific question.

6 BY MR. JONES:

7 Q. Yes or no: Can TVT mesh cause chronic
8 voiding dysfunction in women?

9 MR. MORIARTY: Same objection.

10 THE WITNESS: Again, I mean, the way
11 you're asking it, I cannot answer that question.

12 BY MR. JONES:

13 Q. Yes or no: Can TVT mesh cause nerve
14 damage in women?

15 MR. MORIARTY: Objection.

16 THE WITNESS: Again, the way you're asking
17 it, I cannot answer that question.

18 BY MR. JONES:

19 Q. Yes or no: Can TVT mesh cause death in
20 patients?

21 MR. MORIARTY: I'm sorry. Cause what?

22 MR. JONES: Death.

23 MR. MORIARTY: D-E-A-T-H.

24 MR. JONES: D, starts with a D.

25 MR. MORIARTY: D-E-A-T-H?

1 time for a medical device to market?

2 A. No.

3 Q. Have you reviewed any internal documents
4 related to how the TVT Obturator was developed to
5 market?

6 A. Did you ask internal documents?

7 Q. (Nodding head up and down.)

8 A. I reviewed a few, but I don't recall
9 specifically something about that, no.

10 Q. None specifically that spoke to the time
11 it took to get TVT-O to market?

12 A. No.

13 Q. Have you reviewed the contract between
14 Ethicon and Dr. Ulf Ulmsten?

15 A. No.

16 Q. Are you aware of the oxidizing agents
17 naturally occurring inside a woman's vagina?

18 MR. MORIARTY: Objection. Form.

19 Go ahead.

20 THE WITNESS: Well, am I aware there are?

21 Yes. What they specifically are, I can't say
22 with certainty. I mean --

23

24 BY MR. JONES:

25 Q. Sure. But you're aware there's oxidizing

1 Are you an expert on warnings?

2 A. I'm sorry?

3 Q. I'll withdraw that last question. Are you
4 an expert on warnings?

5 A. Warnings?

6 Q. Warnings related to TVT mesh.

7 A. Warnings related to TVT mesh. I'm trying
8 to consider what an expert in warnings would be.
9 Again, I don't know what an expert in warnings would
10 be.

11 Q. Have you ever drafted an IFU?

12 A. No.

13 Q. Do you rely in your normal course of
14 practice as a physician on IFUs?

15 A. Do I rely?

16 Q. (Nodding head up and down.)

17 A. No.

18 Q. Do you review IFUs before you use the
19 product?

20 A. Yes.

21 Q. Okay. Always?

22 A. Which product?

23 Q. Any product.

24 A. It is my usual practice to review IFUs
25 before using a new product.

1 Q. Thank you. Do you -- are you aware the
2 industry standards that govern what warnings must be
3 in an IFU?

4 A. The industry standards? No, I don't know
5 that --

6 Q. Do you agree that all material risks
7 related to the TVT mesh must be included in the IFU?

8 MR. MORIARTY: Objection. Form.

9 THE WITNESS: I guess define "material
10 risk."

11 BY MR. JONES:

12 Q. It's in your report. How do you use it?
13 I'm using your term.

14 A. I understand. I just wanted to know on
15 how you were using it in your question.

16 (Off record discussion.)

17 Q. I wish I could let you take all day,
18 Doctor, but we're on a tight time frame.

19 A. I apologize. I just don't see where I
20 write on this TVT IFU section the term "material
21 risk." If you would like to point out to me
22 specifically where I'm using it, I'll be happy to cut
23 to the chase for you.

24 Q. Yeah. Why don't you go to page 4? First
25 sentence, page 4.

1 A. Oh. That's under the section of informed
2 consent. Okay. Let me look at that.

3 Q. So I'm using your term "material risk."
4 Okay?

5 A. Okay. But that --

6 Q. See that? You see the words?

7 A. But that -- yeah, I see the word right
8 there.

9 Q. All right. Let me ask my question.

10 A. Go ahead.

11 Q. Is it your opinion that the TVT IFU should
12 include all material risks associated with the
13 device?

14 MR. MORIARTY: Objection.

15 THE WITNESS: And I know we're under a
16 time restraint, so I'll respect that by
17 answering I can't answer your question, because
18 I use the term "material risk" in my discussion
19 on informed consent between surgeon and
20 patients, not on the discussion in an IFU. I
21 use the term differently.

22 So if you want to define what you mean by
23 "material risk in an IFU," I'll be happy to try
24 to answer your question.

25 BY MR. JONES:

1 Q. Same what you mean in your report when
2 you're discussing it in that section. That's what I
3 mean.

4 A. Oh, I understand.

5 Q. So same question, yes or no. Does the IFU
6 for the TVT need to include all material risks
7 associated with the device? Yes or no or I can't
8 answer the question?

9 MR. MORIARTY: Objection. Form.

10 Go ahead.

11 THE WITNESS: I can't answer the question
12 for IFUs.

13 BY MR. JONES:

14 Q. Does the TVT IFU need to include all risks
15 associated with the device? Yes or no or I can't
16 answer the question?

17 MR. MORIARTY: Objection. Form. Go
18 ahead.

19 THE WITNESS: No.

20 BY MR. JONES:

21 Q. What risk must be included in the TVT IFU?

22 A. The material -- I'm sorry. The risk
23 unique to the device. The risks unique to the
24 device.

25 Q. All --

1 A. 20 to 25 percent.

2 Q. Before 2011, what percentage of your
3 practice was related to operating on patients for
4 stress urinary incontinence?

5 A. Maybe 30, 35 percent.

6 Q. Over the past three years, your usage of
7 transvaginal mesh has decreased, correct?

8 A. Yes.

9 Q. Over the past three years, your usage of
10 TVT mesh has decreased, correct?

11 A. Yes.

12 Q. You no longer use transvaginal mesh to
13 treat pelvic organ prolapse whatsoever, correct?

14 A. Correct.

15 Q. Have you ever used any mesh products
16 transvaginally since the year 2000 that are not made
17 by Ethicon?

18 A. No.

19 Q. Do you treat mesh complications?

20 A. Yes.

21 Q. What percentage of your practice is
22 related to mesh -- treating mesh complications?

23 A. A very small amount. Less than 5 percent.

24 Q. How many -- have you removed mesh from a
25 patient before?